

INDIANA STATE DEPARTMENT OF HEALTH

Public Readiness & Emergency Preparedness (PREP) Act

What Health Care Providers Need to Know:

Overview

During a public health emergency, the Public Readiness and Emergency Preparedness Act ("PREP Act") gives immunity from lawsuits for manufacturers, administrators, and distributors of vaccines, as well as other qualified persons (i.e., health care and other providers) who prescribe, administer, or dispense countermeasures, unless they were acting with willful misconduct.

Under PREP Act declarations, the United States Department of Health and Human Services (HHS) Secretary removes financial risk barriers for everyone in the "vaccination chain."

When did it become law and when can it be used?

The PREP Act was enacted in 2005 by Congress. The authority to issue a PREP Act declaration does not depend on other types of emergency declarations being issued. The PREP Act was enacted primarily to address pandemic influenza threats by providing broad liability protection of "covered persons" after a declaration by the Secretary for "covered countermeasures."

What is a declaration?

A declaration includes the determination of a threat or credible risk, recommendation for action, and the category of diseases, health conditions or health threats. It also includes the effective time period, the covered population, the geographic area of administration, and any limitations.

What is a covered counter-measure?

A covered countermeasure may include vaccines, antidotes, medications, medical devices or other FDA regulated assets used to respond to pandemics, epidemics, or any biological, chemical, radiological, or nuclear threat.

Who is covered under the PREP Act?

- ° *Manufacturers* of countermeasures;
- ° *Distributors* of countermeasures;
- ° *Program planners* of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure);
- ° *Qualified persons* who prescribe, administer, or dispense countermeasures (i.e., healthcare and other providers); and
- ° Officials, agents, and employees of any of these entities or persons are also covered persons.

A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

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What is covered under the PREP Act?

Covered persons are protected from any liability for any loss with any causal relationship to any stage of the administration of a covered countermeasure. There are exceptions for willful misconduct and for claims that fall outside of the time frame and geographic limits stated in the declaration.

In addition, health care providers to be covered must report a serious injury or death from vaccine administration within seven days of its discovery to the Vaccine Adverse Events Reporting System (VAERS) (1-800-822-7967, <http://vaers.hhs.gov/contact.htm>).

Have declarations been issued before?

In January 2007, the Secretary of HHS issued a PREP Act declaration for the H5N1 Pandemic Influenza Vaccine. This declaration has been amended three times. In 2008, there were PREP Act declarations for Anthrax, Botulism, Pandemic Antiviral, Small Pox, and Acute Radiation Syndrome Countermeasures. In 2008, there was also a PREP Act declaration for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices. The Pandemic Antiviral Countermeasure declaration was amended in April 2009.

Is the H1N1 vaccine covered under the PREP Act?

Yes. In June 2009, the Secretary amended the PREP Act to include H1N1 vaccine.

If providers are immune from liability, how are people compensated for an injury from the countermeasure?

The PREP Act removes the right to recover in a lawsuit for persons injured by a covered countermeasure, unless the person can prove willful misconduct that resulted in injury.

The PREP Act provides compensation to eligible individuals injured by countermeasures in the event of designated public health emergencies. The federal government has allocated funds for compensation for this program. Compensation includes out-of-pocket medical expenses, lost wages, and a death benefit to survivors.

The government develops a list of adverse events that may be related to the vaccine. The conditions that appear on this list within the time window given are presumed to be causally related to the countermeasure, and are compensated.

Where can I go for more information on the PREP Act?

The federal Department of Health and Human Services (HHS) has a website where you can get more detailed information on the PREP Act. It is:

<http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>.